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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---------------------------------|-----------------|----------------------|---------------------------------|-----------------|
| 10/087,929 | 03/01/2002 | Clarence N. Ahlem | 202.8 | 7989 |
| 26551 | 7590 08/01/2003 | | | |
| HOLLIS-ED | EN PHARMACEUTIC | ALS, INC. | EXAMI | NER |
| 4435 EASTGATE MALL SUITE 400 | | | ÇAZI, SABIHA NAIM | |
| SAN DIEGO, | CA 92121 | | ART UNIT | PAPER NUMBER |
| | | ·- | 1616 DATE MAILED: 08/01/2003 | 4 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| , | | Application No. | Applicant(s) | | | |
|--|--|---|---|--|--|--|
| | | 10/087,929 | AHLEM ET AL. | | | |
| Office Action Summary | | Examiner | Art Unit | | | |
| | • | Sabiha Qazi | 1616 | | | |
| | The MAILING DATE of this communication app | | | | | |
| Period fo | | | | | | |
| THE I - Exter after - If the - If NO - Failu - Any r earne | ORTENED STATUTORY PERIOD FOR REPLINALING DATE OF THIS COMMUNICATION. Isions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a replinal period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing dispatent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | Responsive to communication(s) filed on 01 i | March 2002 | • | | | |
| 1)□ | • | nis action is non-final. | | | | |
| 2a) □ | , | | resecution as to the morits is | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| • | on of Claims | | | | | |
| | 4) Claim(s) <u>1-45</u> is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| · | Claim(s) is/are allowed. | | | | | |
| · | Claim(s) is/are rejected. | | | | | |
| • | Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) <u>1-45</u> are subject to restriction and/or election requirement. | | | | | | |
| · · · | on Papers The energiacetics is objected to by the Evening | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Applicant may not request that any objection to the drawing(s) be field in abeyance. See 37 CFR 1.05(a). 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | |
| * S | 3. Copies of the certified copies of the prio application from the International Buse the attached detailed Office action for a list | reau (PCT Rule 17.2(a)). | · - | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment | r(s) | • | | | | |
| 2) D Notice | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) _ | 5) Notice of Informal F | r (PTO-413) Paper No(s) Patent Application (PTO-152) | | | |
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Claims 1-45 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to method of blood cell deficiency, classified in class 514, subclass 169, 170, 172, 178, 179, 180, 182.
- II. Claims 16-19, drawn to compounds of formula V, classified in class 552, subclass (various).
- III Claims 20-24, drawn to compounds of formula VII, classified in class 552, subclass (various).
- IV Claims 25-32, drawn to compounds of formula IX, classified in class 552, subclass (various).
- IV. Claims33-45, drawn to a method of treating symptoms, classified in class 514, subclass 169, 179, 182.

 The inventions are distinct, each from the other because of the following reasons:

Inventions of Group 1, V and II, III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

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another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case process for using the product as claimed can be practiced with another materially different product.

Inventions of group I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mode of operations.

Because these inventions are distinct for the reasons given above, the search required for Group I is not required for Group II to V, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: See the compounds claimed in claim 31.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from the elected group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 16, 20, 25, and 33 are generic.

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A telephone call was made to Attorney Daryl D. Muenchau on 7/31/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha

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Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on every business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

SABIHA QAZI, PH.D

PRIMARY EXAMINER

July 31, 2003